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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/780,601 | 02/19/2004 | Ching-Hsiang Hsu | 001409.00011 | 3910 |
| 22907 | 7590 | 10/20/2004 | EXAMINER | |
| BANNER & WITCOFF 1001 G STREET NW SUITE 1100 WASHINGTON, DC 20001 | | | FORD, VANESSA L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | |

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-------------------------------|----------------------------|--|
| Office Action Summary | Application No. 10/780,601 | Applicant(s) HSU ET AL. | |
| | Examiner Vanessa L. Ford | Art Unit 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 3-7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 8-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2/19/2004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election of Group I, claims 1-2 and 8-12 filed September 24, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 3-7 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-2 and 8-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-2 and 8-12 are drawn to an isolated microorganism strain, *Lactobacillus rhamnosus* GM-020 deposited at the China Center for Type Culture Collection under CCTCC NO.: CCTCC M 203098 and compositions containing the *Lactobacillus rhamnosus* GM-020 strains.

Because it is not clear that cell lines possessing the properties of *Lactobacillus rhamnosus* GM-020 are known and publicly available or can be reproducibly isolated

from nature without undue experimentation and because the claims require the use of a suitable deposit for patent purposes a deposit in a public repository is required. Without a publicly available deposit of the above *Lactobacillus rhamnosus* GM-020, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event.

Applicant's referral to the deposit of *Lactobacillus rhamnosus* GM-020 on page 5 of the specification is an insufficient assurance that all required deposits have been made and all the conditions of 37 CFR 1.801-1.809 have been met.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by the International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application. These requirements are necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and full street address of the depository is required.

If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the

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criteria set forth in 37 CFR 1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

- (a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;
- (b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;
- (c) the deposits will be maintained in the public repository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and
- (d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and during the term of deposit. Viability may be tested by the repository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of biological material not made under the Budapest Treaty must be filed in the application and must contain:

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- 1) The name and address of the depository;
- 2) The name and address of the depositor;
- 3) The date of deposit;
- 4) The identity of the deposit and the accession number given by the depository;
- 5) The date of the viability test;
- 6) The procedures used to obtain a sample if test is not done by the depository; and
- 7) A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the *Lactobacillus rhamnosus* GM-020 described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d.1216, 227 USPQ (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-2 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by or under 103(a) as obvious over Gill et al, (*WO 99/10476 published March 4, 2004*).

Claims 1-2 and 8 are drawn to an isolated microorganism strain, *Lactobacillus rhamnosus* GM-020 deposited at the China Center for Type Culture Collection under CCTCC NO.: CCTCC M 203098 and compositions comprising the *Lactobacillus rhamnosus* GM-020 strains.

Gill et al teach *Lactobacillus rhamnosus* bacteria and compositions comprising the bacteria (see the Abstract and page 3). Claim limitations such as "which is used for treating obesity and complications thereof" and "wherein the complication is selected from the group consisting of hypercholesterolemia, atherosclerosis and coronary heart disease" are being viewed as limitations of intended use.

Gill et al do not specifically teach a composition comprising *Lactobacillus rhamnosus* GM-020 have CCTCC NO: CCTCC M 203098 . However, in the alternative the strains of Gill, et al appear to be obvious or analogous variants of the claimed vaccine strains. It would have been obvious to one of ordinary skill in the art at the time

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the invention was made to include the bacteria strains of Gill et al in a compositions because the *Lactobacillus rhamnosus* of Gill et al appear to be the same as the claimed *Lactobacillus rhamnosus* bacteria.

4. Claims 1-2 and 8 are rejected under 35 U.S.C. 102(b) as anticipated by or under 103(a) as obvious over Bukowska et al, (WO 99/07827 published February 18, 1999).

Claims 1-2 and 8 are drawn to an isolated microorganism strain, *Lactobacillus rhamnosus* GM-020 deposited at the China Center for Type Culture Collection under CCTCC NO.: CCTCC M 203098 and compositions comprising the *Lactobacillus rhamnosus* GM-020 strains.

Bukowska et al teach *Lactobacillus rhamnosus* bacteria and compositions comprising the bacteria that can be use to lower cholesterol (see the Abstract). The claim limitation "which is used for treating obesity and complications thereof" is being viewed as limitations of intended use.

Bukowska et al do not specifically teach a composition comprising *Lactobacillus rhamnosus* GM-020 have CCTCC NO: CCTCC M 203098. However, in the alternative the strains of Bukowska et al appear to be obvious or analogous variants of the claimed vaccine strains. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the bacteria strains of Bukowska et al in a compositions because the *Lactobacillus rhamnosus* of Bukowska et al appear to be the same as the claimed *Lactobacillus rhamnosus* bacteria and can be used reduce cholesterol level (see the Abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-2 and 8-12 are rejected under 35 U.S.C. 103(a) as unpatentable over Bukowska et al, (WO 99/07827 published February 18, 1999) in view of Tamki et al (Mokuzai Gakkaishi, March 1997, Vol. 43, No. 1, p. 90-95).

Bukowska et al teach *Lactobacillus rhamnosus* bacteria and compositions comprising the bacteria that can be use to lower cholesterol (see the Abstract). The claim limitation "which is used for treating obesity and complications thereof" is being viewed as limitations of intended use.

Bukowska et al do not teach *Auricularia polytricha* (mushrooms).

Tamki et al teach that rats fed a diet that included *Auricularia polytricha* have a lower level of VLDL and LDL cholesterol.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to add *Auricularia polytricha* to a composition comprising *Lactobacillus rhamnosus* bacteria because both have been shown to lower cholesterol levels in animals. It would be expected barring evidence to the contrary that

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a composition that included *Auricularia polytricha* and *Lactobacillus rhamnosus* bacteria would be effective in reducing cholesterol levels.

6. Claims 1-2 and 8-12 are rejected under 35 U.S.C. 103(a) as unpatentable over Bukowska et al, (WO 99/07827 published February 18, 1999) in view of Yang et al (*Biotechnology Letters*, August 2002, Vo. 24, No. 16, p. 1319-1325).

Bukowska et al teach *Lactobacillus rhamnosus* bacteria and compositions comprising the bacteria that can be use to lower cholesterol (see the Abstract).

Bukowska et al do not teach *Auricularia polytricha* (mushrooms).

Yang et al teach that *Auricularia polytricha* included in the diet results in lower cholesterol levels. The claim limitation "which is used for treating obesity and complications thereof" is being viewed as limitations of intended use.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to add *Auricularia polytricha* to a composition comprising *Lactobacillus rhamnosus* bacteria because both have been shown to lower cholesterol levels. It would be expected barring evidence to the contrary that a composition that included *Auricularia polytricha* and *Lactobacillus rhamnosus* bacteria would be effective in reducing cholesterol levels.

Status of the Claims

7. No claims allowed.

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Pertinent Prior Art


8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure (*European Journal of Clinical Nutrition*, 2000 and U. S. Patent No. 6,214, 336 published April 10, 2001).

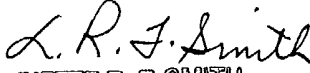
9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Vanessa L. Ford
Biotechnology Patent Examiner
October 8, 2004


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